Analysis of NMFS Biological Opinion for Malathion

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August 29, 2008

Topics:

- Use Patterns
- Use of monitoring data
- Context of monitoring results
  - Why monitoring data is more appropriate
- A potentially better modeling tool – WARP
- Fish toxicity
- Invertebrate toxicity
- Population model

Use Patterns

Historical Use Categories for Malathion:

- USDA Sponsored Programs
- General Agriculture
- Public Health Mosquito Control (Adulticide)
- Home and Garden
- Forestry

Use Patterns - USDA Sponsored Programs

There are three USDA-sponsored programs that have or currently use malathion:

- Boll Weevil Eradication Program (BWEP)
- USDA Fruit Fly Suppression Program
- USDA Grasshopper Control Program

The BWEP accounts for the overwhelming majority of malathion usage in the United States.

All three of these programs include extensive environmental monitoring components. When problems are identified, program adjustments have been made to ensure the protection of aquatic life.

Use Patterns - USDA Boll Weevil Eradication Program

- The BWEP was developed to eradicate the boll weevil from the U.S.
- Application of a ULV formulation of malathion to large acreages by air and by ground (0.3 – 1.22 lbs ai/A).
- The BWEP is applicable only to cotton growing regions of CA; it is not applicable to WA, OR or ID.
- USDA completed its BWEP treatments in CA in 1991. Currently, the cotton-growing areas located within the Southern Desert Valleys are being monitored to detect any boll weevil reintroductions. In the last 17 years, since eradication was accomplished, only 1 boll weevil has been detected in CA. If boll weevils are found in the monitoring traps, a few localized treatments of malathion may be necessary to eradicate any small reinfestation.
- USDA does not anticipate that it will be necessary to make additional applications of malathion in CA.

Use Patterns - USDA Fruit Fly Programs

- Wide area applications of an unregistered ULV/bait formulation control MedFly (0.09 – 0.18 lbs ai/A).
- This use is not supported by Cheminova.
- According to USDA, malathion as an aerial spray will not be carried out anymore over urban areas since Cheminova does not support the use.
- Spinosad is the preferred alternative.
- Growers still have a choice to use a malathion bait in their orchards for certification purposes.

Use Patterns - USDA Grasshopper Control Programs

- This program involves wide area applications of an unregistered ULV/bait formulation (0.62 lbs ai/A) to control grasshoppers and Mormon crickets on federal rangelands in 17 Western States, including CA, ID, OR and WA.

- Outbreaks are usually preceded by several years of gradual increases in grasshopper numbers, followed by a year in which conditions favor grasshopper development.

- Suppression of grasshopper populations may be conducted in response to requests from a Federal land management agency, a local government, or a private group or individual.

- When pesticide use is needed to suppress grasshopper populations, program managers currently have three options: carbaryl, diflurbenzuron, or malathion.

- Before insecticide applications are made, APHIS consults with FWS and land managers to determine what protective measures, if any, are necessary to protect sensitive species and/or sites.

Use Patterns - General Agriculture

- Malathion is registered for use on more than 100 agricultural crops.
- The use on cotton accounts for approximately 90% of the total malathion applied to agricultural crops in the United States, and over 70% of the total acreage applied to agricultural crops.
- The vast majority of the use on cotton is associated with USDA's Boll Weevil Eradication Program.
- Another 3% is applied to alfalfa.
- No other crop accounts for more than 1 percent of the estimated pounds of malathion used in the U.S.

Use Patterns - General Agriculture (continued)

- Cheminova is supporting the use of the ULV, EC and dust formulations of malathion on a wide variety of outdoor agricultural crops.

- 1986 Registration Standard: permitted labels with high use rates and no restrictions on the number of applications and reapplication intervals.

- Early 1990's: Cheminova and IR-4 submitted magnitude of the residue data to support food/feed residue tolerances. Prior to conducting these studies, growers were surveyed to identify the maximum use patterns needed (maximum single application rate, maximum number of applications per year, and the minimum retreatment intervals).

Use Patterns - General Agriculture (continued)

- In the late 1990's, EPA initiated a reevaluation of all older registered chemicals, including malathion. During that time, Cheminova worked with USDA, commodity groups, extension agents and growers to identify minimally acceptable use patterns for malathion for all of the labeled uses.

- With few exceptions, these use patterns are specified in EPA's July 2006 Reregistration Eligibility Decision document for malathion. http://www.epa.gov/pesticides/reregistration/malathion/

  - 4 crop uses: reduced maximum application rates
  - 69 crop uses: reduced maximum number of applications allowed per year
  - 29 crop uses: reduced maximum application rate AND reduced maximum number of applications allowed per year.

- Range of application rates for Non-ULV formulations: 0.5 lbs ai/A – 2.0 lbs ai/A, with a few exceptions

- Range of application rates for ULV formulations: 0.175 lbs ai/A – 1.22 lbs ai/A

Other Recently Voluntarily Cancelled Uses – Many are Urban Uses

- all direct animal and livestock treatments including (goats, hog, horse, poultry, fowl, sheep and cattle: dairy, non-dairy, lactating and non-lactating)
- animal kennels/sleeping quarters (commercial)
- animal premise and barns used for dairy and livestock
- cats
- cattle feed concentrate blocks (non-medicated)
- cattle feedlots and holding pens
- cereal processing plants
- commercial and industrial uses for bagged flour
- commercial storages/warehouses premises (excluding stored grain facilities such as silos)
- commercial transportation facilities - feed/food - empty
- commercial transportation facilities - nonfeed/nonfood
- commercial/institutional/industrial premises/equipment (indoor)
- dairies/cheese processing plant equipment (food contact)
- direct animal treatments including all livestock (horse, hog, sheep, goat, poultry, fowl and dairy, non-dairy, lactating and non-lactating cattle) and pets
- dogs
- edible and inedible commercial establishments
- edible and inedible eating establishments

Other Recently Voluntarily Cancelled Uses – Many are Urban Uses

- edible and inedible food processing plants
- feed rooms
- field or garden seeds
- forest trees (including Douglas fir, eastern pine, hemlock, larch, pines, red pine, spruce, and true fir)
- golf course turf
- greenhouse - empty
- greenhouse - in use
- human clothing (woolens and other fabrics)
- indoor hard surfaces
- indoor premises
- manure piles
- mattresses
- packaged cereals
- pet foods and feed stuff
- poultry houses
- rabbits on wire
- residential dust formulations
- residential lawns (broadcast)
- residential pressurized can formulations
- sewage systems
- stables and pens
- citrus, post-harvest use on dried citrus pulp
- cranberry
- flax
- grape, post-harvest use on raisin drying trays
- lentil
- pea vine
- safflower
- sunflower, pre-harvest
- tobacco

Please note that the residential lawn broadcast use was the subject of a previous voluntary cancellation request dated March 18, 2002.

Use Patterns - General Agriculture (continued)

- The only supported aquatic food use for malathion is on rice. Malathion use on rice in CA is permitted, but CDPR requires a 4-day holding time before releasing treated waters in order to protect aquatic life.
  - Considering the short half-life of malathion, exposure is substantially mitigated.

- Extensive water monitoring studies conducted by CDPR for rice pesticides (including malathion) have confirmed the effectiveness of this measure for reducing residues to established acceptable aquatic life criteria.

Use Patterns - Public Health Mosquito Control

- Because of its low mammalian toxicity, malathion has been an important tool for the control of adult mosquitoes, including those that spread diseases such as West Nile Virus.

- Malathion is currently an option for use in many Public Health Control programs run by states, counties, and municipalities.

  - Label: "For use only by federal, state, tribal, or local government officials responsible for public health vector control, or by persons certified in the appropriate category or otherwise authorized by the state or tribal lead pesticide regulatory agency to perform adult mosquito control applications or by persons under their direct supervision."

- Applications may be made by aerial ULV sprays and by ground sprays (foggers). Application rates range from 0.11 to 0.23 lbs ai/A.

- Malathion is approved for use only as an adulticide; it is not approved for use as a larvacide.

- Environmental Restrictions on Label: "Do not apply over bodies of water (lakes, rivers, permanent streams, natural ponds, commercial fish ponds, swamps, marshes, or estuaries), except when necessary to target areas where adult mosquitoes may be present, and weather conditions will facilitate movement of applied material away from the water in order to minimize incidental deposition into the water body. Do not contaminate bodies of water when disposing of equipment rinsate or washwaters."

Use Patterns - Forestry

- Malathion has historically been used to control forestry pests on a variety of deciduous and evergreen trees
- Forestry uses of malathion are not supported by Cheminova.
- EPA is in the process of removing this use from all product labels.

Use Patterns – Home and Garden

- Emulsifiable concentrate formulations of malathion are currently available to homeowners for outdoor uses on ornamental flowering plants, vegetable gardens, fruit trees, ornamental shrubs and ornamental trees.

- These products may also be used for homeowner mosquito control and as a perimeter treatment around residential buildings (limit 2 foot swath).

- Use rates range from 0.000085 lb ai/ft^2 to 0.0003 lb ai/ft^2

Use Patterns – Home and Garden

- Historically, malathion has been used as a broadcast treatment on homeowner lawns and on golf course turf. However, Cheminova is not supporting these uses.

- EPA is in the process of removing these uses from product labels.

Use of Monitoring Data

- **Relevant data:**
  - Streams
  - Data associated with normal agricultural practices reflecting, or adjusted to reflect, use patterns supported for reregistration.

- **Irrelevant and less relevant data:**
  - Medfly program: large-scale applications over urban areas
    - None since 1991
    - Cheminova is not supporting this use

  - Boll Weevil: specialized for limited purposes
    - No further applications planned in CA (the only relevant state)
  - Urban: residential uses on flower beds, vegetable gardens, trees, and shrubs are allowed, but broadcast treatments to home lawn and golf course treatments have been eliminated

Washington State – Salmonid Bearing Streams Median Concentrations and Detection Rates (ppb)

Site	2003	2004	2005	2006
Thornton Creek	-- (0%)	-- (0%)	-- (0%)	-- (0%)
Marion Drain	0.014 (10%)	0.028 (20%)	0.021 (30%)	0.018 (13%)
Sulphur Creek Wasteway	0.02 (5%)	0.016 (13%)	0.023 (10%)	-- (0%)
Spring Creek	0.013 (5%)	0.012 (16%)	0.034 (3%)	0.015 (6%)
Lower Yakima Watershed	0.017 (6%)	0.019 (16%)	0.023 (16%)	-- (0%)

Washington State – Salmonid Bearing Streams Maximum Concentrations (ppb)

Site	2003	2004	2005	2006
Thornton Creek	nd	nd	nd	nd
Marion Drain	0.024	3.1	0.021	0.018
Sulphur Creek Wasteway	0.020	0.024	0.023	---
Spring Creek	0.013	0.030	0.034	0.015
Lower Yakima Watershed	0.024	3.1	0.022	---

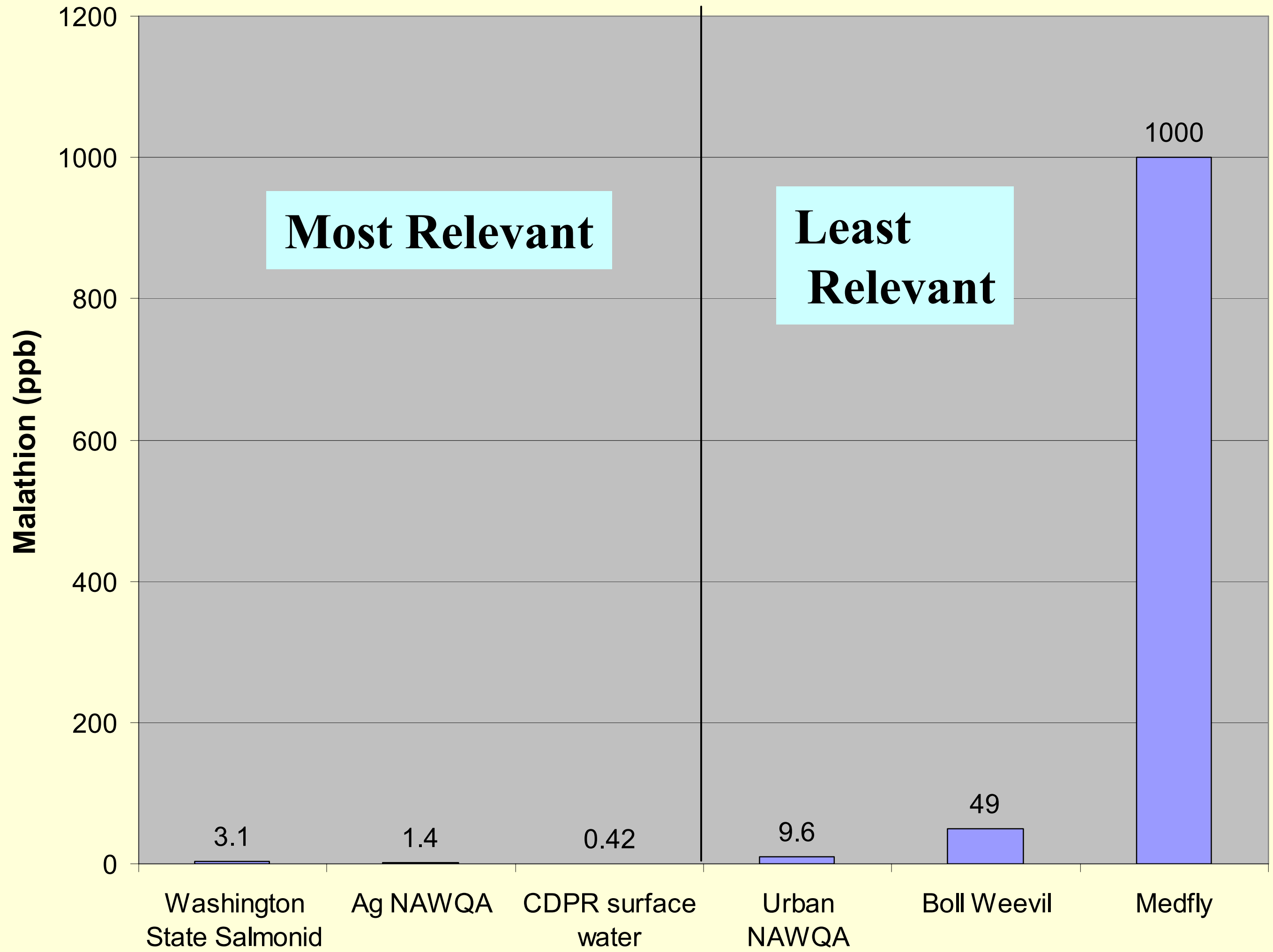
Other Monitoring Data

Sites	Mean (ppb)	Maximum (ppb)
NAWQA (CA, ID, OR, WA)	0.049	1.35
CDPR	0.054	0.42

Other Monitoring Data

- Oregon: Of >100 samples, only 1 was > 0.1 ppb
- Idaho: Maximum value of 1.2 ppb
- Washington State: pesticides in “small streams”, a few detects <0.1 ppb

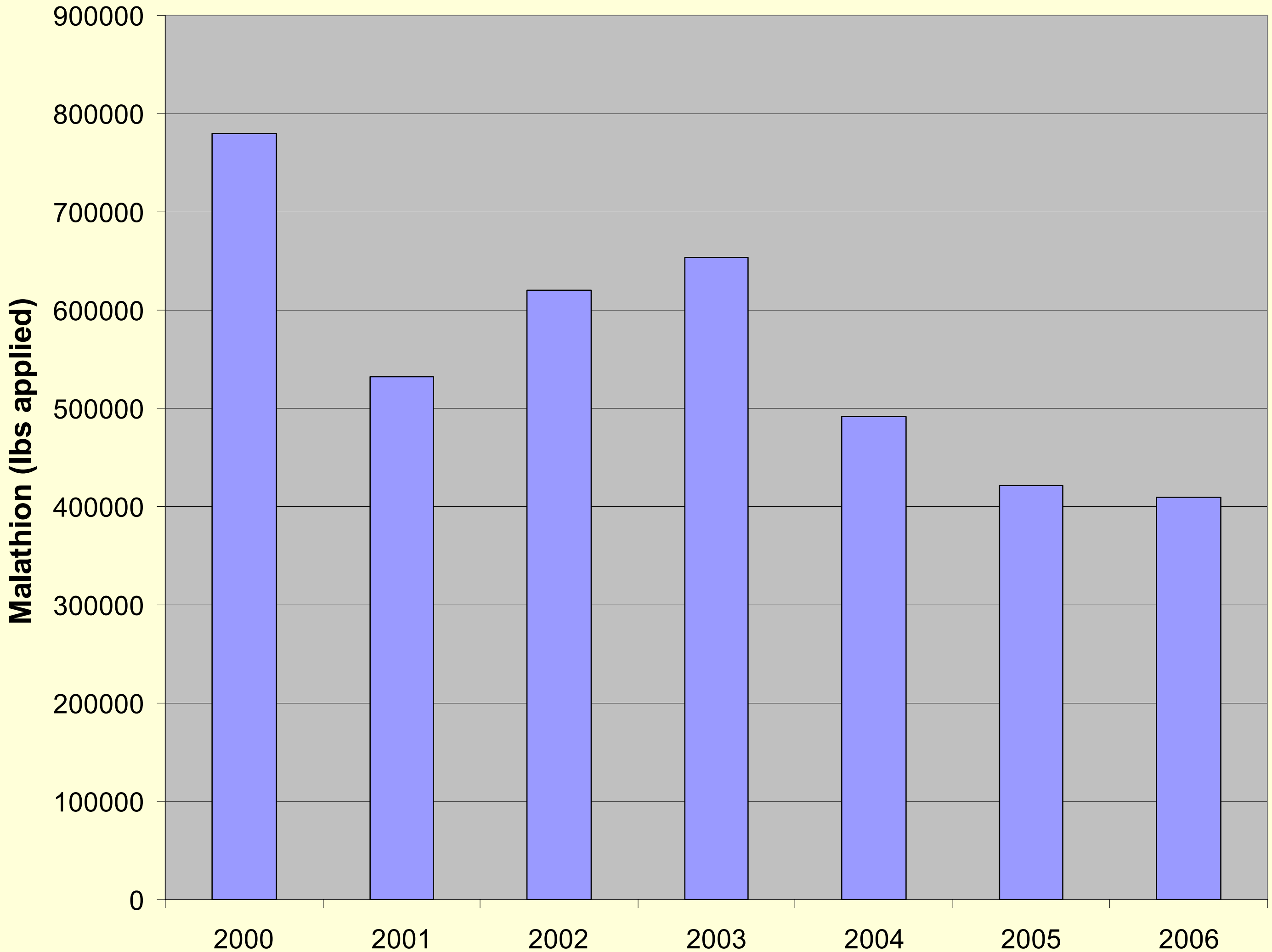
Context of Monitoring Results – Max Values



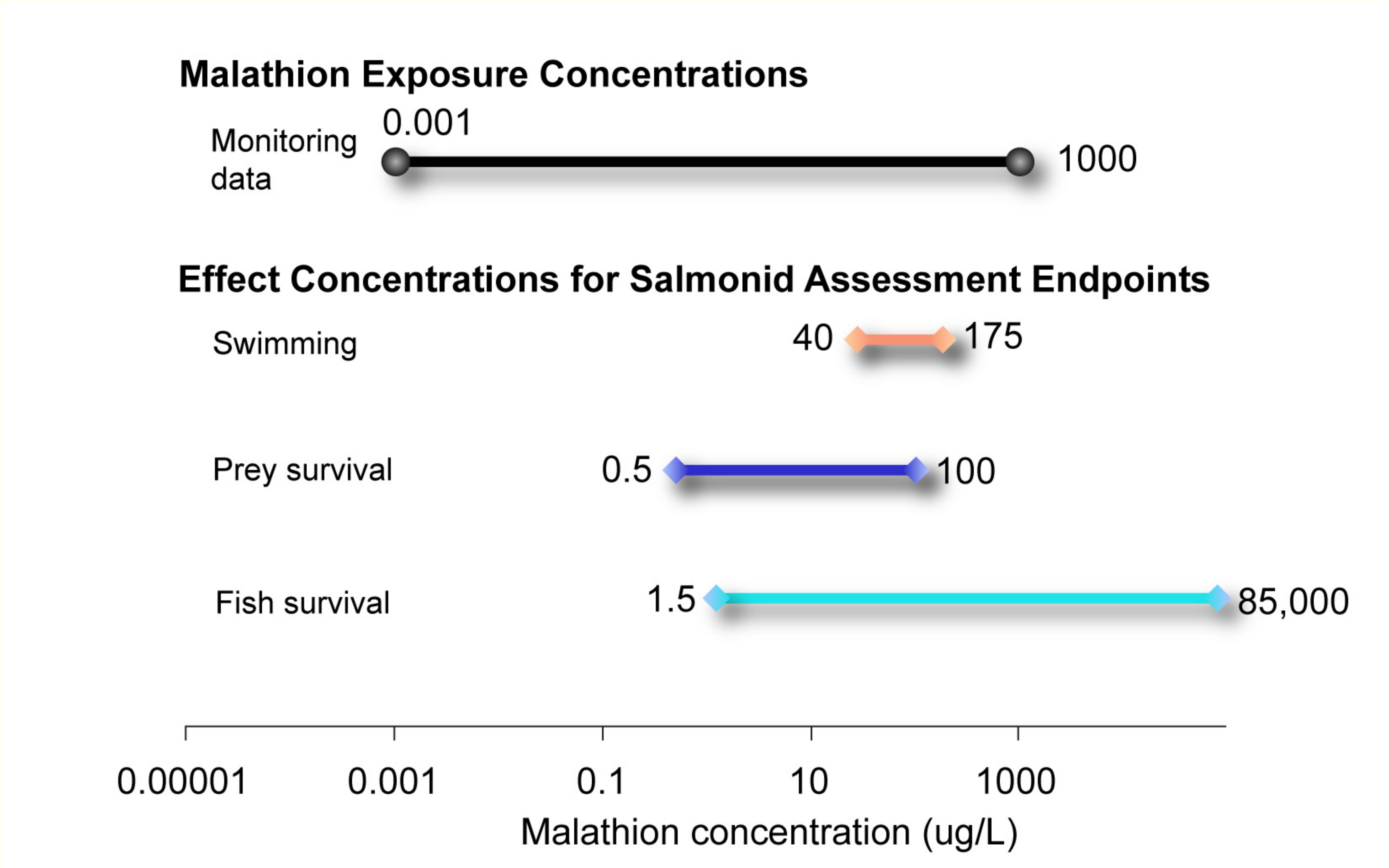
Caveat to Monitoring Data: Mitigation Measures Not in Place During Monitoring Period

- **Data do not reflect recent changes to supported use patterns**
- **Data do not reflect the new buffer zones that are being implemented**
  - 25 feet for non-ULV applications
  - 50 feet for ULV applications
- **Significant reductions are possible with buffer strips**
  - Many application sites already have natural buffer strips without the label language

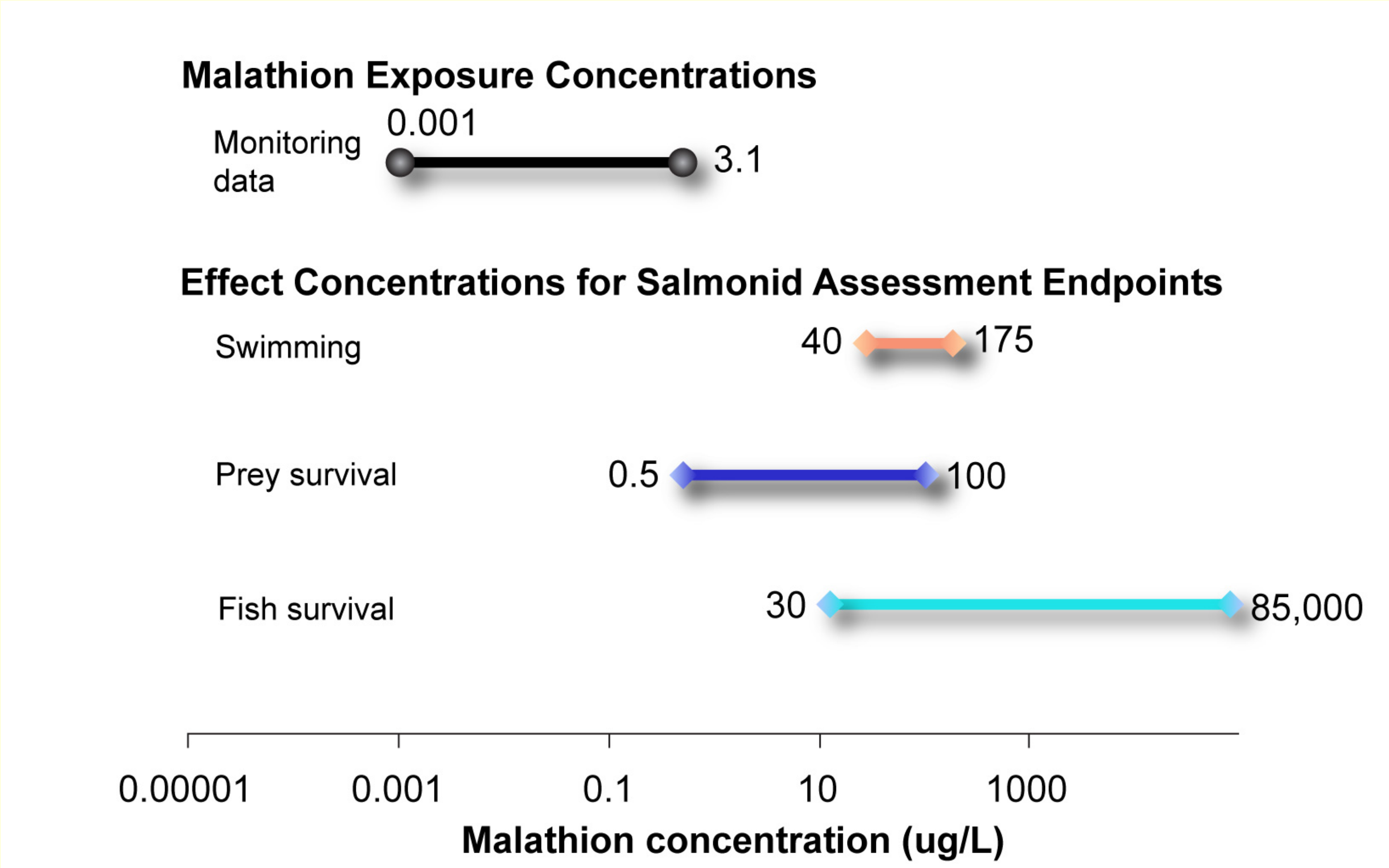
Malathion Usage is Decreasing in California

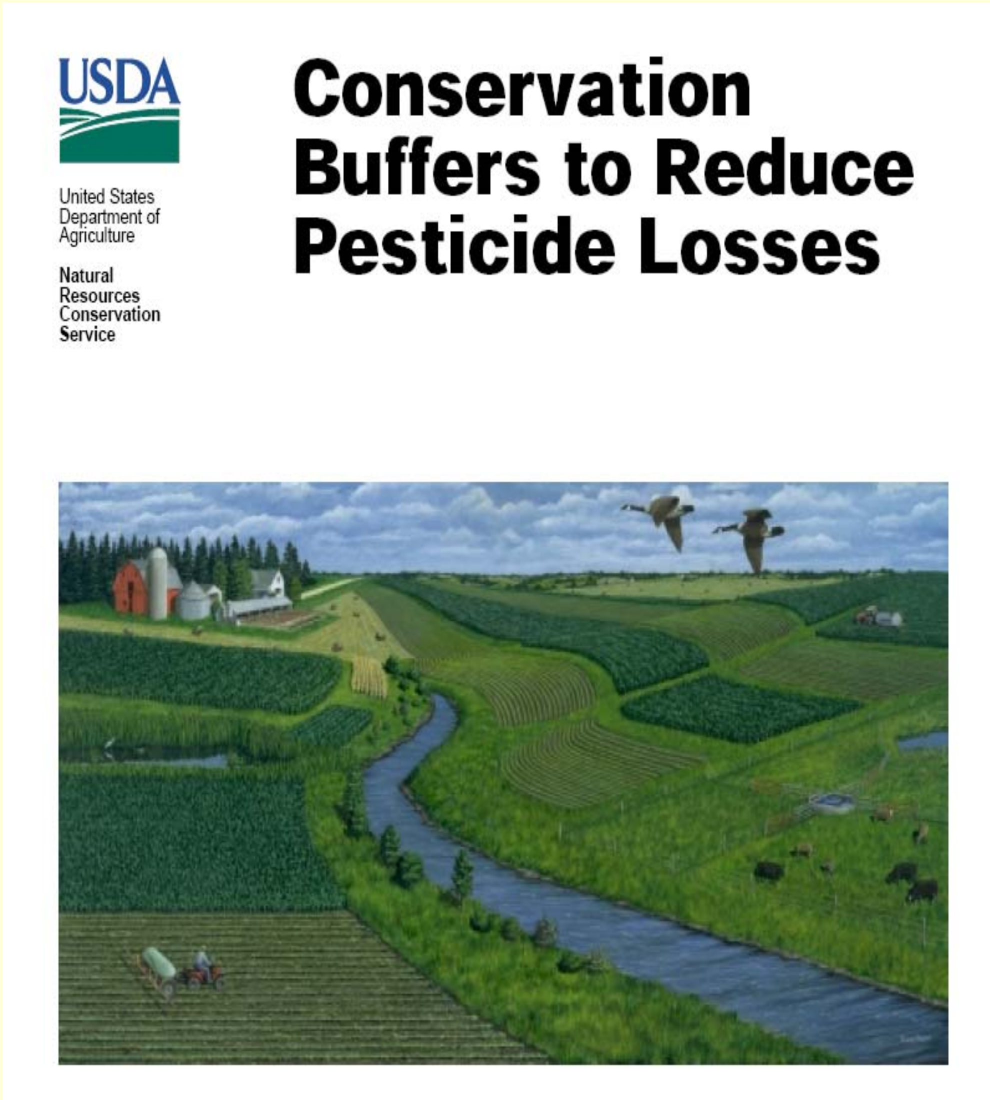


Conclusions from NMFS Assessment



Revised Conclusions Using Highest Quality and Relevant Data




USDA

United States
Department of
Agriculture

Natural
Resources
Conservation
Service

Conservation Buffers to Reduce Pesticide Losses

- **Reviewed studies on effectiveness of buffer strips:**
  - While results are variable, the percent of pesticide trapped in buffer strips ranges from 10-100% for pesticides with K_{oc} values similar to malathion (plot strips from 15-100 feet)

PRZM-EXAMS Modeling

- **Developed for an entirely different purpose:**
  - Farm pond far different than moving water body, even if the DANC is larger
    - Flowing water will disperse the pesticide more quickly
  - Worst-case spray drift – 10 mph wind perpendicular to pond
  - Upper-end fate inputs (e.g., 3x measured aerobic soil metabolism half-life)
  - Highest use rates assumed
  - Worst-case soil and slope assumptions
  - No vegetative buffer strips assumed

Further Comments on PRZM-EXAMS Modeling

- **Comment on 90th percentile values is misleading:**
  - Values from model are not true "90th percentile" values
  - EPA calculates the highest one-day, 21-day and 60-day averages in each simulation year (typically 36 years)
    - The 90th percentile represents the upper-90th percentile of the highest value from across the years
    - For a 36-year simulation, this actually refers to:
      - Peak: 99.97th percentile (only 3 days in 36 years are higher)
      - 21-day: 99.4th percentile (only 4 periods are higher)
      - 60-day: 98.3rd percentile (only 4 periods are higher)

EFED's Characterization of Modeling

- "The screening models, when used according to standard operating procedures with adequate data, generally predict EECs that are higher than most, if not all, analogous concentrations in the environment resulting from labeled uses."

  Source: Declaration of Dr. Norm Birchfield in Washington Toxics Coalition matter. Birchfield, 2003

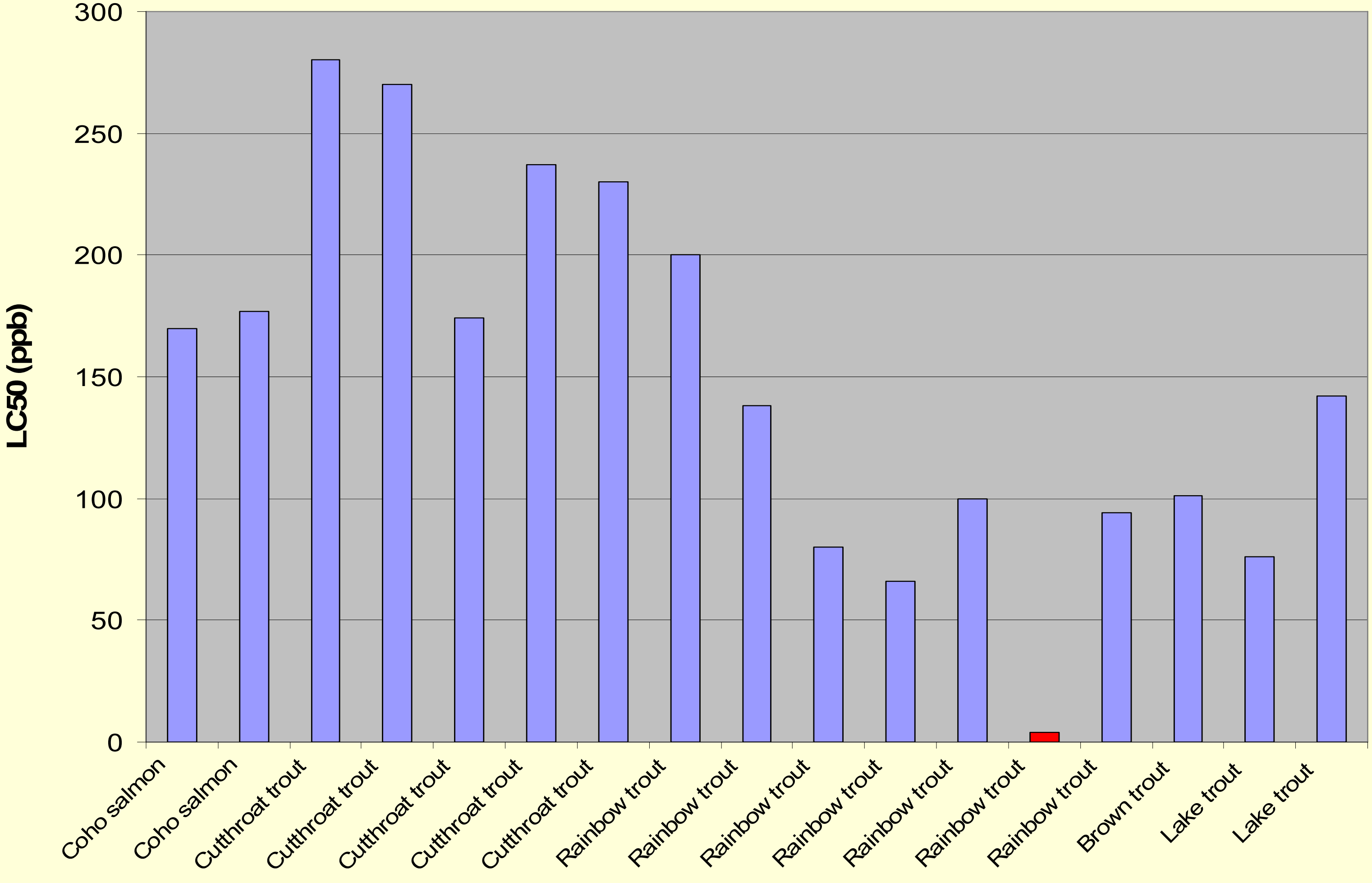
- **In OP cumulative assessment, EPA developed more realistic surface water estimates:**
  - Max: 0.015 ppb for Pacific Northwest
  - Max: 0.0083 ppb for North Central Valley Fruitful Rim

(Reiss, R. Declaration in Washington Toxics Coalition matter)

Better Modeling Tool for this Application

- **USGS Watershed Regression Model (WARP)**
  - Specifically developed for streams
  - Uses measured data to estimate distribution of concentrations, including upper percentiles
    - Considers use data, physical watershed characteristics, weather, soil properties, hydrologic parameters, agricultural management practices
  - Published results for atrazine, metolachlor, cyanazine, alachlor, and trifluralin
    - Can be adapted for other pesticides

Fish Toxicity: Variation in Salmonid LC_{50} Values



Basis for Single Outlier – 1968 Study

Toxic Effects of Odorous Trace Organics

John W. Smith and Sotirios G. Grigoropoulos

A contribution submitted to the Journal *on May 18, 1968, by John W. Smith, Sr. Research Asst., and Sotirios G. Grigoropoulos, Prof. of Civ. Eng., both of the Environmental Health Research Center, Univ. of Missouri-Rolla, Rolla, Mo.*

ORGANIC micropollutants in water may originate from several sources, including industrial and domestic wastes, accidental spillage, agricultural runoff, and bioresistant metabolic byproducts of the natural biota. The USPHS, in recognizing the importance of trace organics in drinking water, has set the maximum permissible limit of chloroform soluble organics at 200 μg/l. Many of the trace organics possess an odor potential and could cause problems of an esthetic nature. Of greater importance, however, is the health hazard represented by these organic micropollutants. This threat is emphasized by the recovery of carcinogenic substances from drinking water in Japan [1] and Germany,[2] and the large-scale fish kills on the lower Mississippi River due to the buildup of a pesticide in the fish.[3] Sproul and Ryckman [4] and Sletten [5] found that trace organics recovered from Missouri River water, both raw and treated, were toxic to rainbow trout at high concentrations (milligrams per liter range) over a short exposure time (4 days); the long-term effect of these materials at lower concentrations was not evaluated. Because trace organics are not completely removed from surface waters by ordinary water treatment practices and subsurface waters are not usually treated in any manner, the presence of these organic micropollutants could represent a serious health threat to the water consumer.

Scope and Objectives

The principle objectives of this investigation are the recovery of organic micropollutants from subsurface and surface Missouri waters; the characterization and identification of these substances; the evaluation of their toxic effects, both acute and long-term; and the development of methods for their destruction or removal.

In a previous article,[6] the authors reported on the recovery and partial characterization of organic micropollutants from several subsurface waters, and the evaluation of the carbon adsorption method with regard to the number of filters required for the effective recovery of organic materials. This article reports on continuing studies to characterize further the trace organics and evaluate their acute and long-term toxic effects.

Recovery of Organics

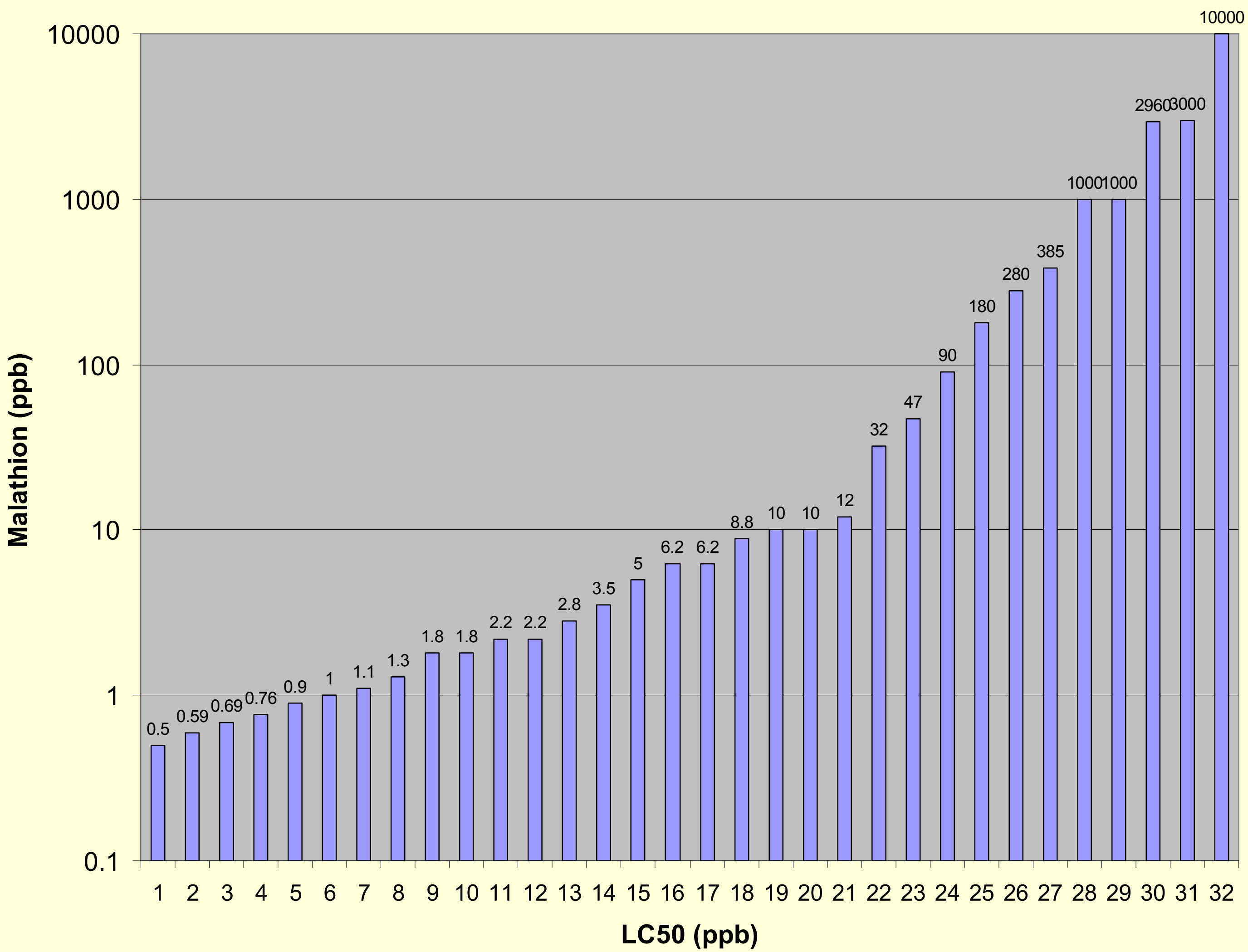
Organic micropollutants were recovered [6] from subsurface and surface waters using the carbon adsorption method. A spring and two deep wells were sampled using a modified carbon

969

Smith and Grigoropoulus (1968)

- Malathion formulation with 57% active ingredient
- Components of this 1968 formulation are unknown
- Current products require lower impurity levels compared to older products
- EPA and California Department of Fish and Game rejected the study for use in risk assessment

Wide Distribution of Aquatic Invertebrate LC50s



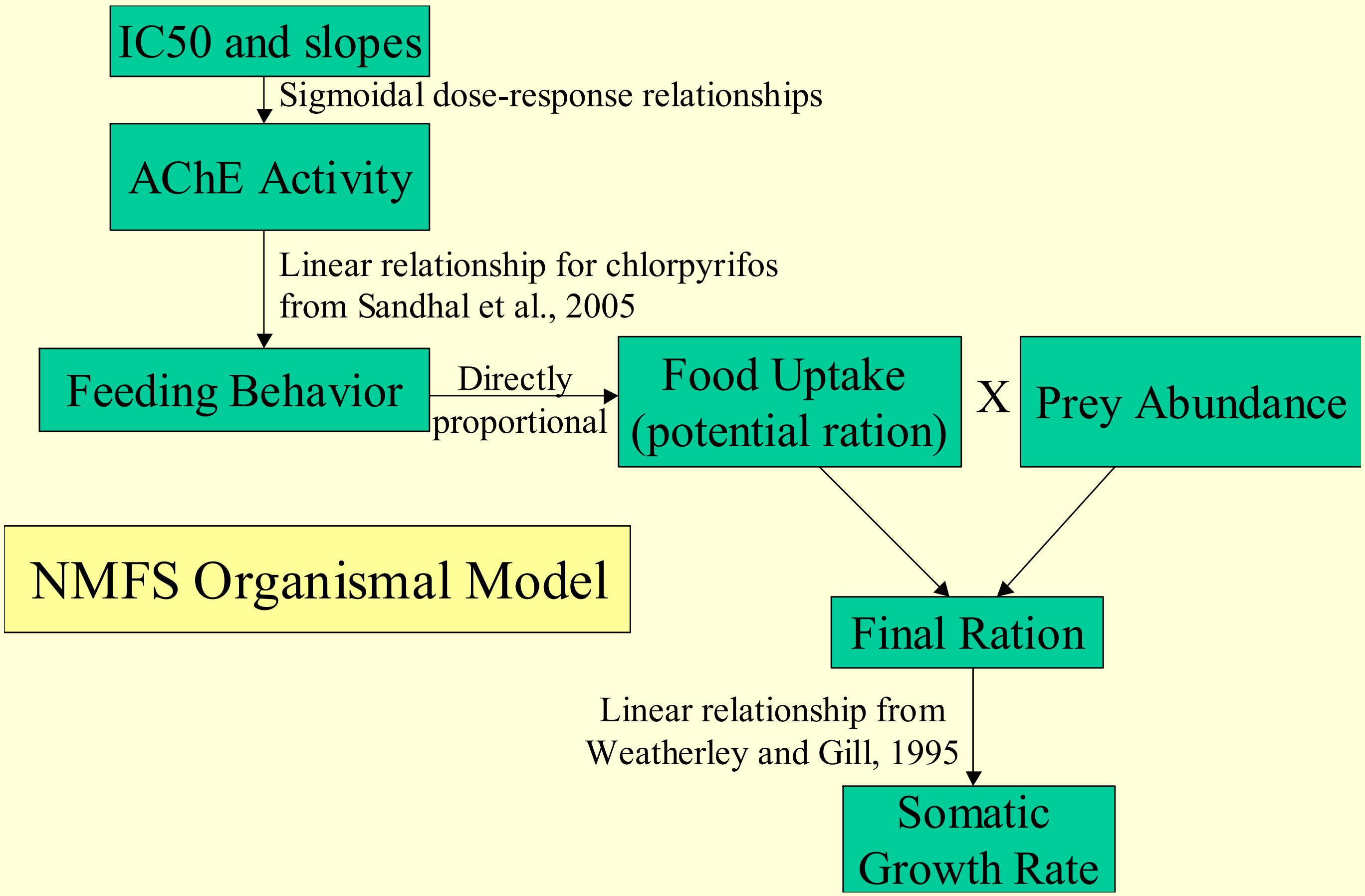
Mesocosm Studies – Boll Weevil Eradication Program

- **Stewart Creek, Fayette County, Alabama (Kuhajda et al., 1996)**
  - 12 and 8 acre cotton fields within 25 feet of pond
  - 9 applications in 1993 and 15 in 1994
  - Malathion levels from 0.88-31.1 ppb
- **Conclusion:**
  - “Within the fish community, numbers of individuals did not show any depression in the experimental locations during spray periods relative to the Control; in fact numbers were greatest for the Downstream location for all time periods except for spray Year 1, where the control location averaged just one more specimen.”

Mesocosm Studies – European Study

- **Study design**
  - Conducted in large concrete pond at laboratory
  - Concentrations of 1.2-30 ppb
- **Conclusion**
  - "… there was no direct impacts on periphyton, phytoplankton, chlorophyll a, macrophytes, macroinvetebrates, emergent insects and functional endpoints."
  - "transient direct treatment related reductions in certain zooplankton species, however the majority of zooplankton species remained unaffected."
  - "no apparent impact of the overall function of the ecosystem."

Population Model



Comments on Population Model

- **Fish lethality slope of 4.5 was based on outdated, organochlorine data:**
  - OPP developed a probit slope of 9.95 using “more current” pesticides
    - EPA: “The probability of mortality for a pesticide with a 9.95 slope is again exponentially less than the original analyzed slope of 4.5” (EPA, 2004, p.10)
  - EPA also developed a revised probit slope for “more current” pesticides of 9.95 for prey abundance
    - Use of this slope will substantially change the prey abundance effect from malathion

Comments on Population Model (cont.)

- **Prey abundance EC_{50} was based on the median EC_{50} for chlorpyrifos was multiplied by 1.2 for malathion**
  - The source of the 1.2 multiplier is unclear

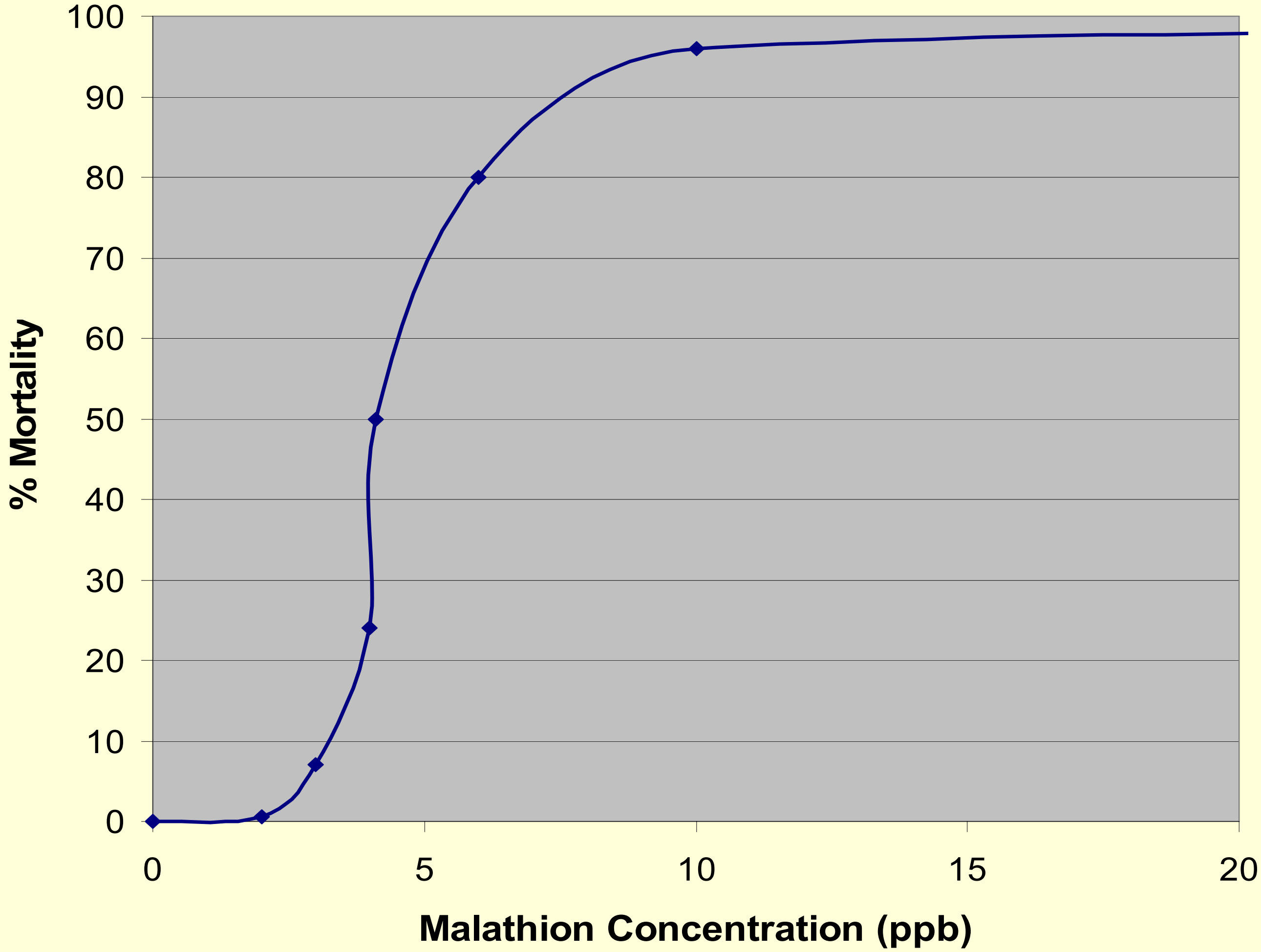
- **IC_{50} values for AChE activity area also based on a chlorpyrifos value (Sandahl et al., 2005)**
  - No basis to assume this value for malathion
  - Malathion has been shown to be the least potent of all the OPs to inhibit AChE activity in mammals
  - Not clear where IC_{50} value of 2.0 from Sandahl et al. comes from – value appears to lie between 1.2 and 1.8 in Figure 1 of original paper.

Comments on Population Model (cont.)

- **There are two mesocosm studies for malathion with higher EC_{50} concentrations**
  - These should be used for the prey abundance value instead of extrapolating from the chlorpyrifos study.

- **Fish lethality value based on obsolete study discussed earlier**

Even with Faulty Inputs, Population Model Shows Little Effect at Peak Concentrations (<3ppb)



Summary

- **Malathion LC_{50}s for fish $\geq$30 ppb**
  - Concentrations above this level are extremely rare
- **Invertebrate LC_{50}s range from 0.5-100 ppb**
  - Mesocosm studies show no population level impacts to fish and very little to invertebrates
- **Population model shows little impact at peak concentrations found in streams**
  - With corrected inputs, the potential impact would be even less

References

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